REMARKS

Claims 1-4 and 6-34 are all the claims pending in the application. Claims 27-34 are withdrawn from consideration by the Examiner. Claim 5 is canceled.

Reconsideration and review of the claims on the merits are respectfully requested.

Claim Rejections – 35 U.S.C. § 102

A. Claims 1, 4, 5, 15-17, 22, 23 and 26 are rejected under 35 U.S.C. § 102(e) as assertedly being anticipated by Tapolsky et al for the reasons given in the Office Action.

Applicants respond as follows.

Claim 1 is amended to incorporate the subject matter of Claim 5, now canceled. Claim 1 now recites: A solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising:

(a) a therapeutically effective amount of at least one herbal active agent or homeopathic active agent, wherein the herbal active agent is selected from the group consisting of a bioactive herb extract, a tincture, an essential oil and mixtures thereof; and

(b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition.

Entry of the amendment is respectfully requested.

The Examiner's position appear to be that the present invention is anticipated because among the active agents taught by Tapolsky there is included thymol which is obtained from thyme oil and eugenol which is obtained from clove oil. However, Applicants point out that the

present definition of the herbal active agent now introduced from Claim 5 excludes the active agents taught by Tapolsky which are single compounds as opposed to a bioactive herb extract, which term is always recognized in the art as referring to a mixture and never a single compound.

More specifically, Tapolsky claims a water-soluble pharmaceutical carrier device comprising a layered flexible film having a first water-soluble adhesive layer to be placed in contact with the mucosal surface and a second, water-soluble non-adhesive backing layer, and a pharmaceutical or combination of pharmaceuticals incorporated in the first or second layer. The first water-soluble adhesive layer comprises hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose; and the second water-soluble non-adhesive backing layer comprises hydroxyethyl cellulose. However, Tapolsky does not mention herbal extracts or bioactive oils as possible herbal medications or homeopathic active agents. Furthermore, only films formed from water soluble polymer solutions by solvent casting are described.

In no place in Tapolsky's patent is compression molding disclosed, and all the text and examples describe films made by solvent casting. Only water soluble components have been specified suitable for adhesive surface, which include water soluble poly(acrylic acids). Preferably the active agents are in the non-adhesive layer.

Applicants note that herbal medications mean a bioactive extract or oil that is a natural mixture of many molecules that act as a collective. This is in contrast to common drugs that are based on a well defined single molecule that can be synthesized or isolated from a natural source. For example, paclitaxel, is a new drug for treating cancer isolated from the yew tree. It is a

single molecule isolated from the extract of the tree that is composed of hundreds of molecules where some of them may have biological activity and some may not. In relation to the present invention, the yew extract that contains the natural composition of many compounds would be included in the designation as a herbal medication while paclitaxel is not, since it is a chemically produced drug molecule.

Tapolsky mentions geraniol as a possible active agent to be included in the device, however geraniol is a single molecule that is isolated from a plant much like paclitaxel.

The Examiner is kindly directed to the relevant paragraphs describing the "pharmaceutical component" in Tapolsky's invention which are listed beginning at col. 7, line 13, to col. 8, line 12. All of the mentioned components are single, well defined molecules that can be prepared synthetically or isolated and purified from natural sources such as plants, animals, etc. No herbal extract or homeopathic actives are mentioned in Tapolsky.

Therefore, the rejection under 35 U.S.C. §102(e) should be withdrawn, and such is respectively requested, since Tapolsky does not teach the use of a homeopathic active agent or the use of a herbal active agent selected from the group consisting of a bioactive herb extract, a tincture, an essential oil or mixtures thereof.

B. Claims 1, 4-7, 15-17, 22 and 23 are rejected under 35 U.S.C. §102(b) as assertedly being anticipated by Roreger et al. with evidence provided by Lawless for the reasons given in the Office Action.

Applicants respectfully traverse the rejection.

The Examiner admits that Roreger teaches a film comprising both an anionic water-soluble polymer and a cationic water-soluble polymer and simply fails to give due cognizance that for bioadhesion there is required a charged anion and since Roreger has a cation-anion pair, there is no bioadhesion since there is no stand alone charged anion to effect the same.

Since the components taught by Roreger do not constitute a solid bioadhesive carrier as required according to the present invention, said rejection should also be withdrawn.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

Claim Rejections – 35 U.S.C. § 103

A. Claims 1-5, 15-17, 22, 23 and 26 are rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over Tapolsky et al for the reasons given in the Office Action.

B. Claims 1-11, 15-17, 19, 22, 23 and 26 are rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over Tapolsky et al in view of Iyer at al and Friedman et al (US 6,197,305) with evidence provided by Lawless for the reasons given in the Office Action.

C. Claims 1-6, 12, 15-17, 22, 23 and 26 are rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over Tapolsky et at in view of Friedman et al in view of Shuch at al for the reasons given in the Office Action.

Applicants respectfully traverse the rejections.

Tapolsky cannot constitute a primary reference for the reasons given above as well as for the following reasons.

Tapolsky describes non-adhesive films releasing single molecule active agents. The films are made by casting an aqueous solution of the polymer composition onto a surface which is exposed to 90°C to 130°C to dry the solution and to obtain the film (Example 1). The solution contains about 90% of water and the other ingredients. All other Examples in Tapolsky describe different compositions of the films with all using the method described in Example 1 for making the film. Examples 1 through 10 describe various compositions of non-adhesive films made by the process described in Example 1. Further examples 11-19 describe compositions of adhesive films made by the process described in Example 1. Example 20 describes a clinical study showing a 45 minute to 60 minute adhesion to mucosal tissue.

Applicants note, however, and respectfully point out to the Examiner that Tapolsky's process of making adhesive films is NOT relevant for the inclusion of bioactive agents which are sensitive to heat or evaporate at high temperature. Herbal compositions and essential oils are highly sensitive to heat, and easily evaporate even when exposed to a temperature of 50°C for a short period of time. Example 1, column 9, lines 16-17, of Tapolsky states, "The solution was then casted on a glass substrate and film dried for 8-9 min. at 130°C." Furthermore the process described in many of the examples e.g. Examples 3, 8, 9 etc. describe that, "The solution was then casted on a polyester substrate and dried overnight at 90 °C."

It is absolutely clear that Tapolsky does not teach the incorporation of herbal medications or even heat sensitive drugs, but, to the contrary, Tapolsky describes a process which is incompatible with the incorporation of such active ingredients.

In contradistinction, the process of the present invention is based on a full awareness of the sensitivity of herbal compositions that contain many various active agents that together are responsible for the overall biological effect, and is based on an awareness of the fact that heat will evaporate or destroy some of the components and thus significantly deteriorate the active herbal or even may result in a toxic composition due to excessive heat. Furthermore, the use of aqueous solution for herbal compositions such as essential oil must provide methods for solubilization or dispersion to obtain a uniform distribution in the final film. Furthermore, exposure of essential oil or herbal compositions to heat an aqueous medium will hydrolyze some actives in the herbal composition. Tapolsky does not teach how to keep content uniformity, reproducibility in active distribution particularly with actives that are composed of more than one molecule as is the case of herbal medications with both hydrophobic and hydrophilic components. The process described in the present invention absorbs the herbal extract or essential oil into the carrier powders without any heat or aqueous solution as well as teaching the preparation of a tablet which is made by compression of powders at room temperature without any heat or evaporation process that may affect the herbal composition.

Thus it will be realized that combination of Tapolsky with the active ingredients from any of the secondary references cited by the Examiner would not result in the products of the present invention since the process of Tapolsky would inactivate and destroy said active ingredients.

For the foregoing reason, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

In addition, it is respectfully submitted that a person skilled In the art would not combine the teachings of any of the secondary references with Tapolsky since the secondary references focus on synergistic effects among herbal compositions or other advantages of the active compounds and not on the specific use to treat oral disorders. Friedman describes a synergistic antibacterial effect when mixing various herbal agents. However, the present invention is not specific to antimicrobial agents which actually have little effect on mucosal ulcers which require anti-inflammatory action.

Iyer (US 5,939,050) describes improved MIC of antimicrobial compositions by mixing two or more components which can be used for various applications. Shuch describes oral dental formulations that contain Vitamin C and ubiquinone as unique combinations that have an advantage for dental care.

As stated before, the present invention does not include these single molecules which are not herbal compositions and which have not been proven to help in oral care such as treatment of canker sores.

In summary, Tapolsky describes adhesive films that are prepared in a process that would destroy the herbal agents of the present invention, and therefore Tapolsky cannot teach or suggest, alone or in combination, the novel and unobvious compositions of the present invention.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

AMENDMENT UNDER 37 C.F.R. § 1.116
U.S. Application No. 10/083,413 **Q63391**

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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